



Sil-Med Corporation

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SIL-MED®

510 (k) Summary

Company: Sil-Med Corporation
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Telephone: (508) 823-7701
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Contact Person: Karen K. Sylvia
QA/QC Manager

Trade Name: Penrose Drain
Common Name: Flat Silicone Drain
Classification Name: Apparatus, Single Patient Use, Portable,
Non-Powered (878.4680)
Description: Passive Wound Drain
Predicate Device: Davol Gravity Drain

Intended Use: Post-operative passive drainage of serosanguineous
fluids away from soft tissue operative site.

Biocompatibility Testing:

Test	Results
Rabbit Pyrogen Test	non-pyrogenic
Hemolysis-Rabbit Blood	non-hemolytic at 2.02% Hemolysis
Salmonella typhimurium REVERSE Mutation ASSAY	non-mutagenic
Kligman Maximization Study (Cottonseed Oil Extract)	Grade I - weak allergenic potential (not considered significant)
Kilgman Maximization Study (Sodium Chloride Extract)	Grade I - weak allergenic potential (not considered significant)
USP CLASS VI	Satisfied the requirements of USP XXII Biological Test for Plastics, Class VI-121°C
ELUTION TEST	non-cytotoxic
USP MUSCLE IMPLANTATION STUDY IN RABBITS WITH HISTOPATHOLOGY (90 Days)	met USP requirements

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Penrose Drain

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Sil-Med Corporation's Penrose Drain is dimensionally equivalent to the Davol Gravity Drain, except Davol offers both 12" and 18"; Sil-Med Corporation offers 18" only. Both have inner diameter teeth to prevent the drain from collapsing. Both devices have a Radiopaque stripe. Davol Gravity Drains are sold sterile and non sterile. Sil-Med Penrose Drains are sold sterile only. The intended use of both drains is equivalent.

Date: 1/10/96